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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,103	01/05/2004	Connie S. Schmaljohn	033267-023	1344
21839	7590	10/07/2005	EXAMINER	
BUCHANAN INGERSOLL PC (INCLUDING BURNS, DOANE, SWECKER & MATHIS) POST OFFICE BOX 1404 ALEXANDRIA, VA 22313-1404			HINES, JANA A	
		ART UNIT		PAPER NUMBER
		1645		

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/751,103	SCHMALJOHN ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 January 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) _____ is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-4 and 6-21 are drawn to a polynucleotide vaccine composition, classified in class 424, subclass 246.1.
 - II. Claims 5, 22-48 are drawn to a polynucleotide vaccine composition comprising a first and second nucleic acid operatively linked to a promoter and a method for eliciting an immune response, classified in class 424, subclass 278.1.
 - III. Claims 49-50 are drawn to a method for using a *Bacillus anthracis* antigen, classified in class 435, subclass 485.
 - IV. Claims 51-56 are drawn to a method for using a *Bacillus anthracis* antigen to induce an immune response in a subject providing an expression cassette containing a first and second nucleic acid, classified in class 435, subclass 320.1.
2. The inventions are distinct, each from the other because of the following reasons:
 - (i) Inventions I and II are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper because these products appear to constitute patentably distinct inventions. Group I is drawn to a polynucleotide vaccine composition while Group II is drawn a polynucleotide

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vaccine composition comprising a first and second nucleic acid operatively linked to a promoter and a method for eliciting an immune response. The groups are directed to the vaccine compositions that are physically, structurally and functionally different, and are therefore patentably distinct, each group from the other. For instance, the a polynucleotide vaccine composition comprising a first and second nucleic acid operatively linked to a promoter and a method for eliciting an immune response is unlike the composition of Group I. Therefore, one group is not required to practice the other. Each group comprises separate and distinct products that are not disclosed as being essential to the utility of the invention.

Furthermore, searching the inventions of groups I and II would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus different compositions require different searches. A search for first and second nucleic acid operatively linked to a promoter and a method for eliciting an immune response is not necessary for a determination of novelty and unobviousness of unrelated group I. Moreover, a search of group II is not required to identify the composition of group II. Furthermore, the composition of group I may be known even if the composition of group II is novel. In addition, the technical literature search for the composition of group I and the composition of group II are not coextensive, e.g., the composition of group I may be characterized in the technical literature prior to discovery of the composition of group II.

(ii) Inventions II and either III or IV are related as distinct methods because they are different methods with different method steps; reagents; functions and each method results in different final outcomes. First, the instant specification does not disclose that these methods would be used together. The methods are unrelated as they comprise distinct steps and utilize different products which demonstrate that each method has a different mode of operation. Each invention performs its function using structurally and functionally divergent material. For instance, the method for eliciting an immune comprises administering a polynucleotide vaccine composition comprising a first and second nucleic acid operatively linked to a promoter drawn from group II is unlike the methods of group III and IV. Both groups III and IV use expression cassettes which is unlike the vaccine composition. Furthermore, the expression cassettes of groups III and IV comprise different components, for instance only group IV comprises a first and second nucleic acid operatively linked to each other and to control sequences tat direct expression. Thus, the method of group IV is not necessary to practice the method of Therefore the methods are separate and distinct each from the other. Each method is divergent with respect to the reagents used and their associated steps. For these reasons the inventions of groups II, III and IV are patentably distinct.

Furthermore, searching the inventions of groups II, III and IV would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A method for eliciting an immune response, requires a different search, than a method for using a *Bacillus anthracis* antigen. Thus, a search drawn to a method using a *Bacillus anthracis* antigen, is not necessary for a

determination of novelty and unobviousness of the method of group II. Furthermore, the method of group III may be known even if the method of group IV is novel. In addition, the technical literature search for the method of group II and the method of groups III or IV are not coextensive, since, for instance, the method group II may be characterized in the technical literature prior to discovery of the method of group III or IV.

(iii) Inventions I and either III or IV are unrelated because this product and method are not used or otherwise involved in any of the above recited methods. The methods of groups III and IV does not make or use the product of group I. For these reasons the inventions I and III are patentably distinct.

3. The inventions of Groups I-IV have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search any combination of the inventions of Groups I-IV together.

4. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines

September 30, 2005